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**Statement by the Honorable Bobby L. Rush, Chairman
Subcommittee on Commerce, Trade and Consumer Protection
for Legislative Hearing on
H.R. 1706, the Protecting Consumer Access to
Generic Drugs Act of 2009**

March 31, 2009

WASHINGTON, DC — “The subcommittee will come to order. Today’s legislative hearing is on H.R. 1706, the Protecting Consumer Access to Generic Drugs Act of 2009.

“Chairman Waxman and I introduced this bill in the last Congress and the subcommittee held a legislative hearing on May 2, 2007. We have introduced the bill, again, with the intent that it becomes law. H.R. 1706 bans what are known as “exclusion payments,” “reverse payments” or “reverse consideration” in patent settlements between brand-name and generic drug companies. This is a practice in which the brand-name company pays or provides value to the generic company, and the generic company agrees to delay the marketing of its generic drug product.

“The bill is opposed by both PhRMA and most generic companies. The fact that both innovator and generic companies oppose the bill is striking, because brand-name and generic companies are not supposed to agree on anything. Under the regulatory structure of Hatch-Waxman, generic companies are supposed to aggressively challenge the patents of brand-name drug companies in order to bring their products to the market. If they settle, they are supposed to settle by agreeing to an early entry date, not by agreeing to delay entry into the market. Unfortunately, the intent of Hatch-Waxman is being undermined by these uncompetitive legal settlements and consumers are losing out on the considerable savings from generic drugs.

“I want to emphasize several important points in this bill:

“First, the bill is fully supported, on a bipartisan basis, by the Federal Trade Commission. The

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Commission believes a legislative fix is needed, because the courts have thwarted their enforcement efforts. Both Republican and Democratic Chairmen and Commissioners have historically supported Congressional action cracking down on these uncompetitive settlements. This is not a partisan issue.

“Second, the bill does NOT ban all settlements in drug patent cases. Quite the contrary. H.R. 1706 only bans exclusion payments in legal settlements. Brand name and generic companies are still free to settle their disputes. In fact, before the courts invalidated the FTC’s enforcement efforts, drug companies were settling their patent disputes without any exclusion payments. It wasn’t until the court struck down FTC’s enforcement actions in 2005 that these very unique types of settlements came back from the dead.

“Third, these types of settlements are completely unique to the drug industry. They do not appear in any other kind of patent dispute. In all other patent disputes, litigants settle in two ways: (1) the accused infringer pays the patent holder a royalty to market its product, or (2) the parties agree to an early entry date. Only in the drug industry do we see the unusual behavior of a patent holder (the brand name company) suing the accused infringer (the generic company) and then settling *by paying the infringer to stay off the market*. These unique settlements are the result of the equally unique regulatory framework of Hatch-Waxman. I don’t believe that drug companies are acting in bad faith. I believe they are being perfectly logical under their fiduciary duties to their shareholders, and are simply responding to the incentives they face under Hatch-Waxman.

“Lastly, H.R. 1706 will save taxpayers, businesses, and consumers tens of billions of dollars. That is the ultimate purpose of this bill. Congress is currently considering ways to save money as a means to provide affordable health insurance to all Americans. I believe H.R. 1706 can play an important role in reducing prescription drug costs in our economy. We cannot afford to do nothing on these unique, uncompetitive settlements that cost consumers billions of dollars.

“I want to thank all of our witnesses for appearing today in what is the first step of the legislative process. I look forward to an honest, civil and robust discussion and debate. We may not ultimately come to agreement, but I want to emphasize that I am committed to an open dialogue and to further discussion on how we can improve the legislation.

“I yield back the balance of my time.”

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